

Guidelines for Applying for Licence of Nuclear Medicine Facility through eLORA System

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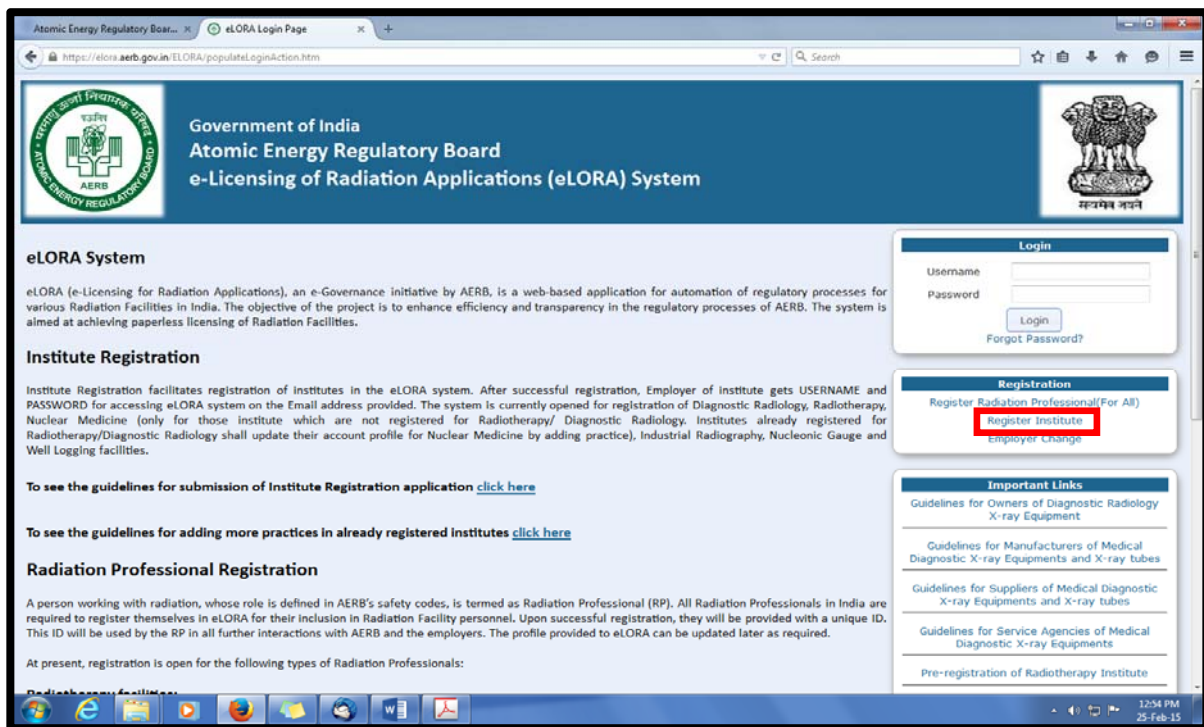
General Guidelines (Applicable for Regularization as well as New)

The practice of Nuclear Medicine in India is governed by the Atomic and Energy Act, 1962 and rules promulgated under the Act. In view of this, AERB issues regulatory consents at different regulatory stages and publishes codes and guides as per the act & relevant rules. To facilitate the mandate, AERB has launched e-LORA (e-Licensing of Radiation Applications), its e-governance application system to facilitate online submission of applications for regulatory consents and establish channel of communication with AERB for other regulatory requirements. All Nuclear Medicine user Institutes are required to use eLORA for obtaining relevant consents and approvals from AERB.

1. Register Your Institute

Note: Those who have already registered their institute through e-LORA for other practices, need not register again. The Nuclear Medicine facility can be updated in their Institute Profile. Guidelines for updation is available in e-LORA Home Page.

Visit our website www.aerb.gov.in. Click on **eLORA**, which is available on website home page. It will redirect you to the following screen of **eLORA HOME PAGE**.



Click on **Register Institute** (see above figure). This will open application form for Institute Registration.

APPLICATION FOR INSTITUTE REGISTRATION

Institute Details | Employer Details | Attachments

All fields marked by * are mandatory

Institute Details

Institute Name*
Institute Type*
Registered with any State/Central Govt auth.*
PAN No.
TAN No.

Address Of Institution

Institute Name
Address Line1*
Address Line2
Landmark
State*
City/District*
PIN*

Address Of Communication

Is Address of Communication same as Address Of Institution?
Address Line1*
Address Line2
Landmark
State*
City/District*
PIN*

Submit Close Reset

Important Note: Guidelines to fill application form for Institute Registration is available on eLORA home page. It is advised to read the guidelines and keep soft copy of required attachments ready before start filling of application form.

Fill the application form as per the guidelines. Important points in each tab are mentioned below:

Tab 1: Institute Details

In **Type of Facility** section, for the field **Practice** select **Nuclear Medicine** and for the **Role** select **Nuclear Medicine Facility**

Tab 2: Employer Details

Name: Fill the complete name of employer as appearing in his/her document for **Proof of Identity/Date of Birth (DOB)** to be attached.

Date of Birth: Fill the DOB as appearing in the proof of identity/DOB to be attached

Document/card for proof of identity and date of birth (of employer): Select one from the drop down. (Soft copy of this is a mandatory attachment).

Document/Card No. (of Proof of Identity/DOB): Must match with the proof of identity/DOB attached

E-mail (O): Will be used to send USERNAME and PASSWORD of your eLORA account and for all future communications. (Make sure to provide correct email address).

Tab 3: Attachments

Upload of following attachments are mandatory:

- ✓ **Proof of Identity and Date of Birth (of employer):** Acceptable documents are as follows:
 - o Passport
 - o PAN card issued by Income Tax Department
 - o Driving Licence issued by RTO
 - o Photo identity document/card having serial number and date of birth issued by Central/State Government or PSU
- ✓ **Proof of Employership:** Example: (i) Joining order as employer, (ii) Board Resolution, (iii) Any Govt./PUC document substantiating proprietorship (iv) Partnership deed (notorised) or (iv) Proprietor's self declaration on institute letter head affixed with institute seal
- ✓ **Upload scan copy of any one of the document (in the relevant position) for the proof of existence of institute:**

- o PAN of Institute
- o TAN of Institute
- o Registration with State/Central/Local Government Authority

Enter the Captcha and submit the application form.

Important Note: Fields marked with * in the application form are mandatory. Application form will not be submitted if any mandatory field left blank.

You will get acknowledgement message upon successful submission of application form. The copy of submitted application (.pdf file) can be downloaded for which link will be provided (pl. note, this link will be active for a shot period). You will also receive an acknowledge mail with the copy of your application form (.pdf file) in your email (email address as provided in the application form).

2. General Requisites

General details of the facility has to be recorded in the system by the following menus;

A. Declare Employees

For every **Nuclear Medicine** facility, having at least one **Nuclear Medicine Technologist**, one **Nuclear Medicine Physician** and an **RSO** is mandatory for obtaining License.

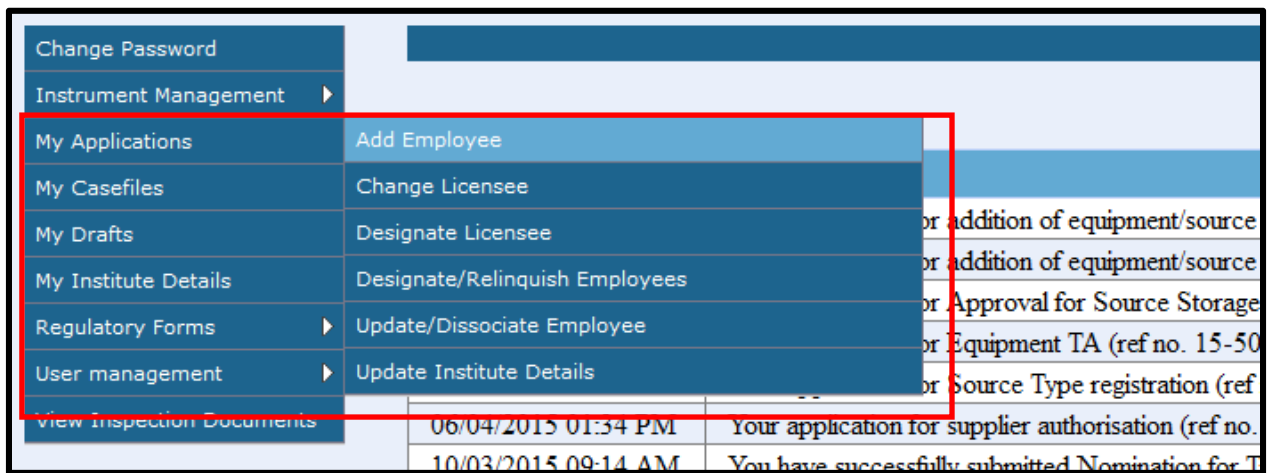
The minimum qualification for the same is given below;

Role of Employee	Eligibility
Nuclear Medicine Physician	Basic: M.B.B.S. Professional: MD in Nuclear Medicine/DNB in Nuclear Medicine /Diploma in Radiation Medicine (DRM) or equivalent.
Nuclear Medicine Technologist	Basic: 10+2 (Science), B.Sc.(Science) as applicable Professional: B.Sc in NMT/ M.Sc or M. Tech in Nuclear Medicine Technology/ M.Sc in Nuclear Medicine/ P.G. Dip in Nuclear Medicine Technology/ Diploma in Medical Radioisotope Techniques (DMRIT)/Diploma in Nuclear Medicine Technology(DNMT), Accredited Nuclear Medicine Technologist(ANMT) or equivalent

RSO	<p>a. RSO eligibility certificate, if passed out RSO examination.</p> <p>b. Certificate of training in an AERB recognized High Dose Therapy facility</p>
-----	--

For adding employees to your institution, please follow the path as;

Menu → **User Management** → **Add Employee** → Select required **Type of Employee** from drop down



Three options are available in drop down for **Type of Employee** as follows;

- ✓ **Radiation Professional** (for **Nuclear Medicine Physicians** and **Nuclear Medicine Technologist**...Note that these people can only be nominated as RSO)
- ✓ **Radiation Worker** (for supporting staffs eg **ward boy, nurse** and **others**)
- ✓ **Non Radiation Worker** (to add Licensee if he is not a radiation worker)

In the form for adding **Radiation Professional**,

- A pop up will prompt you to provide **RP ID** and **DOB** of the personnel which will be available with the person. All other personal details will come automatically.
- Provide Date of Joining (of service in your institute), PMS No. (i.e. complete TLD No.), Department and Designation, Profile (i.e. 'Nuclear Medicine facility') and Professional Role (i.e. 'Nuclear Medicine Physician, Nuclear Technologist')
- Provide Email (O)
- Browse and upload scan copy of joining /confirmation letter of employee and click on **Submit**

ADD Employee

Select Employee Type

Type Of Employee* All fields marked by * are mandatory

Personal Details

Click here to add a RP

Title*

First Name*

Middle Name

Last Name*

Date Of Birth*

Date Of Joining*

Department

Designation

Select profile*

Professional Role*

PMS NO
(Applicable for 'Medical diagnostic x-ray facility', Radiotherapy', Nuclear Medicine only.)

Role
(Applicable for 'Medical diagnostic x-ray facility' only. Role shall be selected based on appropriate qualifications. Refer AERB website for required minimum qualifications.)

Permanent Address

Address Line1*

Address Line2

Select radiation professional [X]

RP registration ID ?*

Date of birth of RP*

Whether the person is also Employer of the institute?* Yes No

Search

Submit Close Reset Education Detail Experience Detail

In the form for adding **Radiation Worker**,

- Provide required personal information of employee viz. Title, Name, Gender & Date of Birth
- Provide required service information of employee viz. Date of Joining (of service in your institute), PMS No. (i.e. complete TLD No.), Department, Designation, Profile (i.e. 'Nuclear Medicine facility').
- Provide address & contact details of employee
- Browse and upload scan copy of joining /confirmation letter of employee and click on **Submit**

Type Of Employee* Radiation Worker

Personal Details

Title* --Please Select--

First Name*

Middle Name

Last Name*

Gender* --Please Select--

Date Of Birth*

Date Of Joining* 7/4/2015

Department

Designation

Select profile*
 Radiotherapy installations
 Supplier of radiotherapy equipments/sources
 Manufacturer of radiotherapy equipments/sources
 Nuclear Medicine Facility
 Supplier of Nuclear Medicine Equipment/Source
 Gamma Irradiation Chamber (Radiation Facility)

PMS NO
(Applicable for 'Medical diagnostic x-ray facility,Radiotherapy,Nuclear Medicine' only.)

Role
(Applicable for 'Medical diagnostic x-ray facility' only. Role shall be selected based on appropriate qualifications. Refer AERB website for required minimum qualifications.)
 Operator-Medical diagnostic x-ray facility
 Medical Practitioner-Medical diagnostic x-ray facility

Education Qualification
(Applicable for 'Medical diagnostic x-ray facility' only.) --Please select--

Attachment for uploading copy of proof of education
(Applicable for 'Medical diagnostic x-ray facility' only.)
 Browse... No file selected. Clear

Permanent Address

Address Line1*

Address Line2

Landmark

In the form for adding **Non Radiation Worker**,

- Provide required personal information of employee viz. Title, Name, Gender & Date of Birth, Father's Name, Educational qualification
- Provide required service information of employee viz. Date of Joining (of service in your institute), ID proof, Department, Designation
- Provide address & contact details of employee
- Browse and upload scan copy of joining /confirmation letter and proof of educational qualification of employee and click on **Submit**

Type Of Employee*	Non Radiation Worker
Personal Details	
Title*	--Please Select--
First Name*	
Middle Name	
Last Name*	
Date Of Birth*	
Gender*	--Please Select--
Date Of Joining*	7/4/2015
Document/card for proof of identity and date of birth*	--Select One--
Document/card No.*	
Father's Name*	
Education Qualification	--Please Select--
Designation	
Department	
Permanent Address	
Address Line1*	
Address Line2	
Landmark	

Important Note: You will not be able to fill further application form for Licence and procurement of sources unless you add employees e.g. **Nuclear Medicine Physician** and **Nuclear Medicine Technologist** as a Radiation Professional of your Institute. Also, declaration and approval of RSO is also a mandatory requirement for Nuclear Medicine.

B. RSO Approval

Availability of RSO in a Nuclear Medicine facility is mandatory. You may obtain RSO approval through e-LORA. Please note that RSO approvals obtained through e-LORA only will be recognised by AERB as valid.

For adding RSO to the facility, please follow the path as;

Menu → **Regulatory Forms** → **Common Forms** → **Nominate RSO** as shown below;

Your Logged in profile is: Nuclear Medicine--Nuclear Medicine Facility

Change Password | Instrument Management | My Applications | My Casefiles | My Drafts | My Institute Details | Regulatory Forms | User management | View Inspection Documents

My Inbox

Nominate RSO

Date and Time	Message
06/04/2015 01:39 PM	Your application for Source Type registration (ref no. 15-5061) is Approved. A
06/04/2015 01:34 PM	Your application for supplier authorisation (ref no. 15-5060) is Approved. App
10/03/2015 09:14 AM	You have successfully submitted Nomination for Trainee Radiographer with Ap

You will be navigated to the following screen for nomination of RSO

Radiation Professional Details

Select Radiation Professional

Radiation Professional* ...

Date of Birth*

Registration ID*

Role of RP*

RSO Status*

e-Mail Id Official*

Education Details

Experience Details

Nominate | Renominate | Renew | Undesignate | Reset | Close

Nominate RSO (for first time approval in the institute):

“Nominate RSO” is applicable for nominating the employee for RSO of the institute for the first time. Select the employee from the List of Values (LOV) indicated in the right side of the Radiation professional label. The details of the selected employee will be populated in the rest of the fields. Choose the button “Nominate”. Click on “Freeze”. Now application form will be generated. You can download the form from the link provided in the message as follows,

Your Application Number is 15-5098

To complete the submission, please upload signed copy of the application. The link is given here
[RSO_Form_20150408115842701.pdf](#)
Download the file, sign the copy and upload it for completing the submission.

[Close](#)

Else you may choose “My Application” to download the same form. A scan copy in PDF format for the first page of the application after signed and affixed with the Institute Seal need to be uploaded and then select “Submit”. After successful approval of the RSO Nomination you (Employer and RSO) will receive a message in their email id as provided in eLORA. A copy of the approval letter will also be emailed to RSO’s email Id. Employer can view the approval copy in “My Application” and also choosing the infrastructure case file.

RSO renewal (renewal on expiry of RSO approval)

Renewal of RSO can be initiated by employer of the facility. From the employee list, only employee can be selected whose RSO status is “Yes”.

Radiation Professional Details

Select Radiation Professional

Radiation Professional* ...

Date of Birth*

Registration ID*

Role of RP*

RSO Status*

e-Mail Id Official*

Education Details

Experience Details

[Nominate](#) [Renominate](#) [Renew](#) [Undesignate](#) [Reset](#) [Close](#)

RSO Renomination (to add or remove roles of the RSO)

Only approved RSOs of the institution can be renominated for addition/removal of roles of the institute. Renomination button will be deactivated for the employee whose RSO status is “Yes” before one month of RSO approval validity.

Click on “Freeze”. Now application form will be generated. You can download the form from the link provided there. Else you may choose “My Application” to download the same form. A scan copy in PDF format for the first page of the application after signed and affixed with the Institute Seal need to be uploaded and then select “Submit”. Status of the application can be viewed from “My Application” and also choosing the infrastructure case file.

RSO Undesignate (to remove the RSO roles completely):

In case, employer wants to withdraw the role of RSO from an approved RSO, the same can be initiated through “Undesignate” option. Only approved RSOs can be undesignated and he/she will no longer be RSO of the institute. However, he/she will continue to be employee of the institute.

In the “View employee list”, the status of RSO will be indicated as “No”. In case the RSO is leaving the Institute, the employer has to “Undesignate” the RSO and then “Dissociate” him/her. A relinquishing letter for the RSO dissociation will be available in RSO approval file and the status of the RSO file will be “close”.

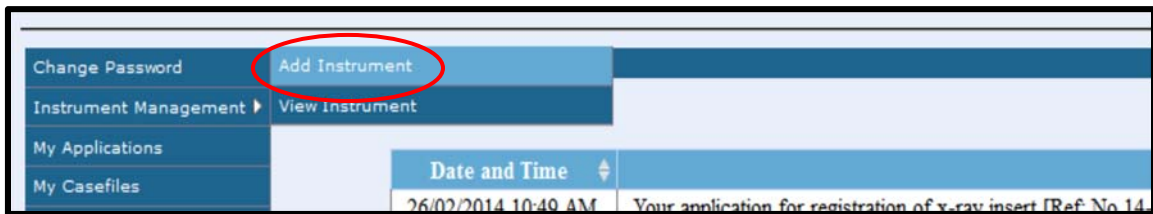
Select	Employee Name	Designation	RSO Status	Licensee Status
<input type="radio"/>	AMIT NIRHALI	Radio Physicist	Pending	No
<input type="radio"/>	VENDHAN SUBRAMANI	Radio Physicist	No	Yes

C. Add Instrument

All Nuclear Medicine facilities require instruments e.g. survey meter, dose calibrators etc for day to day functioning of the facility. The instruments need to be declared in e-LORA. To declare the same follow the path as:

Menu → Instrument Management → Add Instrument/View Instrument

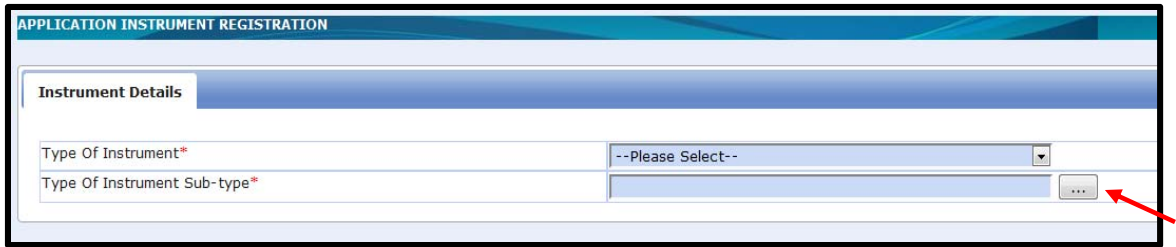
For modification of certain details already available go to View Instrument



Following options are available in Drop Down for Type of Instrument,

- Measuring Tools (Dose Calibrator etc)
- Monitoring Tools (Survey Meter etc)
- QA Tools (Phantoms & other accessories)
- Safety Tools (Safety accessories like Fume Hood, Tongs, Syringe shields etc)

All the instruments has to be declared separately to the system which will store all the details. The LOV for Type of Instrument Sub-type will list out all the relevant instruments as per the selection in the previous field.



Regularization of already existing Nuclear Medicine facilities

Already existing Nuclear Medicine facilities have to regularize their Layout Approval and Licenses of the equipments / installations in eLORA. The following procedure should be adopted:

1. Approval of Layout

Every institution should apply for approval of the layout regularization in the first stage. To apply for the layout, please login to your account. Menus are available to the left of your screen. Go to the menu **Regulatory Forms** → **Nuclear Medicine** → **Site & Layout Plan Approval** as shown below;

Your Role is: **Employer, Licensee**
 Institute Name: **GETWELL SOON2 (MH-20810)**
 Last Successful Login: **21/04/2015**
 Your Logged in profile is: **Nuclear Medicine--Nuclear Medicine Facility**

Change Password			Site & Layout Plan Approval
Instrument Management ▶			Intimation of Available Equipments/Installations
My Applications			Application for Source Procurement
My Casefiles			Source Procurement Intimation
My Drafts	Common Forms		Application for Licence
My Institute Details	Nuclear Medicine		QA/QC Report
Regulatory Forms ▶	Transport		Radiation Survey Report
User management ▶			Application For Decommissioning/Disposal
View Inspection Documents			Application for Decommissioning Intimation
		08/04/2015 03:38 PM	You have successfully submitted Application for supplier authorisation with
		08/04/2015 03:01 PM	Your application for supplier authorisation (ref no. 15-5121) is Approved.

Click on **Site & Layout Plan Approval** and the application form will appear;

Fill up the form as required. Important points in each tab are mentioned below:

Tab 1: List of Available Installation

This Tab will show you the list of all installations (e.g. PET, SPECT, PET-CT, High Dose Therapy etc) available with you and registered with AERB. Check for any discrepancies.

Tab 2: General Details

- **Have you obtained Site and Layout from AERB for all your available installations on or before 31/01/2015?:** Choose 'Yes' as the AERB approval is already available with you and you need to regularize your approval with e-LORA.
- **Layout application submission for:** Choose **New Application** for regularization of existing layout

New Application

- **Application Submission For:** Choose all the installations/equipments as already approved and exercised from the drop down list. Use **Add Row** for multiple selection. Note that **Number of Each Installations** for **LDT, HDT, Beta-Therapy & Non- Imaging Techniques** are by default '1' and can't be modified.

Note: Carefully select all the installations as the radioisotopes and its quantity available to you for permission in the later stages will be based on your selection

NUCLEAR MEDICINE FACILITY APPLICATION FOR SITE AND LAYOUT PLAN APPROVAL

List of Available Installations | **General Details** | Checklist | Attachments

Have you obtained Site and Layout approval from AERB for all your available installations on or before 31/01/2015* ?

Layout application submission for*

Whether technical expert is within the institute?*

Name of the technical expert*

Application Submission For*	Number of Each Installations*
<input type="text" value="Non-Imaging Techniques"/>	<input type="text" value="1"/>
<input type="text" value="HDT(High Dose Therapy)"/>	<input type="text" value="1"/>
<input type="text" value="PET-CT"/>	<input type="text"/>

Add row | Delete row

PET/PET-CT/PET-MRI Details

Proposed combined workload(number of patients/week)* ?

HDT Details

Total number of beds for HDT*

Minimum capacity of single delay tank(litres)*

Whether more than "1" delay tank is indicated in the layout plan?*

Whether plumbing line to the delay tank/sewerage is indicated in the attached layout plan?*

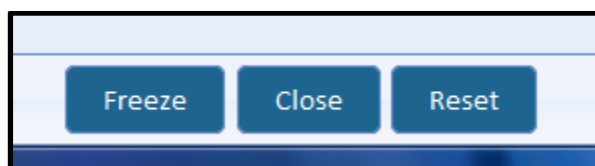
Tab 3: Checklist

Checking the check boxes in the **Checklist** are mandatory for submission. Please go carefully through all the points on the checklist to avoid rejection of application from AERB end.

Tab 4: Attachment

Provide scanned copy of existing AERB approval letter in Other Attachments and approved & signed plans in Site layout plan, Room layout plan & Cross-sectional layout plan.

Please note that on completion of filling up the form you are required to Freeze/Submit the application by clicking on the options available below the screen. For detailed methodology of submission, see guidelines for **RSO Approval**.



Note: All the Site & Layout Approvals obtained before should be regularized by this process only. Separate Site and Layout Approvals in the same institute should be regularized separately.

2. Intimation of Available Equipment

After due regularization of layout, every institution needs to register/intimate the details of the equipment (e.g. PET, SPECT etc) and installations (HDT, LDT, Beta-Therapy etc). Give all the details as sought in the screen and **SUBMIT**.

The system will automatically record the details as provided.

Go through the following screens for representation;

Your Role is: Employer
Institute Name: Advanced Centre for Treatment, Research & Education in Cancer
Last Successful Login: 06/04/2015
Your Logged in profile is: Nuclear Medicine--Nuclear Medicine Facility

Change Password
Instrument Management
My Applications
My Casefiles
My Drafts
My Institute Details
Regulatory Forms
User management
View Inspection Documents

Site & Layout Plan Approval
Intimation of Available Equipments/Installations
Application for Source Procurement
Source Procurement Intimation
Application for Licence
QA/QC Report
Radiation Survey Report
Application For Decommissioning/Disposal
Application for Decommissioning Intimation
Application for Source Storage Facility (ref no. 15-5066) is Approved. Approval No is 15-COMSUPPTR-4362.
Application for Equipment TA (ref no. 15-5065) is Approved. Approval No is 15-COMSUPPTR-4362.
Your application for Source Type registration (ref no. 15-5061) is Approved. Approval No is 15-COMSUPSRCTR-4361.
Your application for supplier authorisation (ref no. 15-5060) is Approved. Approval No is 15-COMSUPPAUTH-4360.
You have successfully submitted Nomination for Trainee Radiographer with Application No. 15-4938 for Mrs. TRAINEE RADIOGRAPHER.

Date and Time

Message to User

06/04/2015 01:39 PM
06/04/2015 01:34 PM
10/03/2015 09:14 AM

Equipment Details

SLA reference no*	<input type="text"/>	...
Installation ID*	<input type="text"/>	...
Model*	<input type="text"/>	...
Supplier*	<input type="text"/>	...
Sr.no*	<input type="text"/>	
Maximum kVp	<input type="text"/>	
Maximum mA	<input type="text"/>	
Date of procurement/available since*	<input type="text"/>	

The duly intimated equipment / installation only will be available for **Application for License**.

3. Application for License

For regularization of equipments and installations already in operation and having valid License from AERB should exercise this option.

Note: PET-CT and SPECT-CT in operation will be having valid Licences from AERB which should be regularized. For other equipments / installations, guidelines for New Application for License should be followed.

To apply for License for the installations, follow the path **Menu** → **Regulatory Forms** → **Nuclear Medicine** → **Application for License** and **Click** as shown below.

The screenshot displays a user dashboard with the following information:

- Your Role is: **Employer, Licensee**
- Institute Name: **GETWELL SOON2 (MH-20810)**
- Last Successful Login: **13/04/2015**
- Your Logged in profile is: **Nuclear Medicine--Nuclear Medicine Facility**

A navigation menu on the right lists several options, with **Application for Licence** circled in red. Below the menu, a table shows a log of recent actions:

Date and Time	Action
08/04/2015 03:38 PM	You have successfully submitted Application for supplier authorisation with ap
08/04/2015 03:01 PM	Your application for supplier authorisation (ref no. 15-5121) is Approved. Ap
08/04/2015 02:58 PM	You have successfully submitted Application for supplier authorisation with ar

The following page will appear on your screen. Fill the same as instructed:

The screenshot shows the 'APPLICATION FOR LICENCE' form with the following tabs: Worker Details, Instrument Details, Installation Details, **General Details**, and Attachments.

The form contains the following fields:

- Have you obtained Licence from AERB for all your available installations on or before 31/01/2015?*
- Licence for*

Both fields have dropdown menus with the option "--Please Select--".



Tab 1: Worker Details, Tab 2: Instrument Details & Tab 3: Installation Details are for information and verification only.

Tab 4: General Details

- **Have you obtained Licence from AERB for all your available installations on or before 31/01/2015?:** Choose 'Yes' as the AERB approval is already available with you and you need to regularize your approval with e-LORA.
- **Date of Issuance:** Give date of issuance of the License.
- **Approval Valid till:** Give date of expiry of the License.
- **Approval Reference No:** Give reference no of the License exactly as given in the same.
- **License for:** Select **Installation**
- **Installation ID:** Select from LOV the installation you want to apply for
- **Type of Installation / Make/ Model / Serial No / Max kVp / Max mA:** Will be auto-populated based on your selection
- **Reference No of QA/QC report:** QA/QC report should be selected from LOV. For guidance to how to upload QA/QC report see the relevant section
- **Reference No of Radiation Survey report:** Radiation Survey report should be selected from LOV. For guidance to how to upload Radiation Survey report see the relevant section.

NUCLEAR MEDICINE FACILITY APPLICATION FOR LICENCE

Worker Details | Instrument Details | Installation Details | **General Details** | Attachments

Have you obtained Licence from AERB for all your available installations on or before 31/01/2015?*	YES	
Date of issuance*		
Approval valid till*		
Approval Reference Number*		
Licence for*	Installation	
Installation ID*		...
Type of Installation		
Make		
Model		
Serial No		
Max kVp		
Max mA		
Reference No of QA/QC report*		... ?
Reference No of Radiation Survey report*		...

Freeze | Close | Reset

Please note that on completion of filling up the form you are required to Freeze/Submit the application by clicking on the options available below the screen. For detailed methodology of submission, see guidelines for **RSO Approval**.

4. QA/QC Report & Radiation Survey Report

Follow the path mentioned below for uploading a QA/QC Report of an Installation / Source,

Menu —→ **Regulatory Forms** —→ **Nuclear Medicine** —→ **QA/QC Report**

Welcome to e-LORA

Your Role is: **Employer, Licensee**
 Institute Name: **GETWELL SOON2 (MH-20810)**
 Last Successful Login: **13/04/2015**
 Your Logged in profile is: **Nuclear Medicine--Nuclear Medicine Facility**

Change Password		Site & Layout Plan Approval	
Instrument Management		Intimation of Available Equipments/Installations	
My Applications		Application for Source Procurement	
My Casefiles		Source Procurement Intimation	DOX
My Drafts		Application for Licence	
My Institute Details		QA/QC Report	
Regulatory Forms	Common Forms	Radiation Survey Report	Message to U
User management	Nuclear Medicine	Application For Decommissioning/Disposal	val with Applicat
View Inspection Documents	Transport	Application for Decommissioning Intimation	ved. Approval No

08/04/2015 03:38 PM	You have successfully submitted Application for supplier authorisation with application no
08/04/2015 03:01 PM	Your application for supplier authorisation (ref no. 15-5121) is Approved. Approval No
08/04/2015 03:59 PM	Your application for supplier authorisation (ref no. 15-5121) is Approved. Approval No

The following screen will appear and the guidelines to fill is given below:

NUCLEAR MEDICINE FACILITY ▶ QA/QC Report

Report Details

QA/QC submitted for*	--Please Select--	?
Installation ID *	--Please Select--	...
Make	Ad-hoc Periodic	
Model		
Serial no		
Name of the technical expert *		...
Any other person involved		...
Date of completion of QA test*		
Upload QA/QC report	Browse... No file selected.	Clear

Tab: Report Details

- **QA/QC submitted for:** Select **Periodic** if you want to upload the QA/QC report in the system. The report will not be reviewed by AERB unless it is referred in relevant applications e.g. License. Only **Periodic** reports can be tagged with the **Application for License**.

Select **Adhoc** if you are prompted or requested from AERB to Upload a QA/QC report. The report will be reviewed by AERB.

- **Installation ID:** Choose **Installation ID** from LOV
- **Make / Model / Serial No:** Will be auto-populated based on your selection
- **Date of completion of QA test:** Give the date of test
- **Upload QA/QC report:** Scan & Upload a Report as per the format prescribed in AERB website

The same path and guidelines should be followed for uploading a Radiation Survey Report

NUCLEAR MEDICINE FACILITY ▶ RADIATION SURVEY REPORT	
Report Details Attachment Details	
Radiation survey submitted for*	--Please Select-- ?
SLA reference no*	--Please Select--
Name of RSO involved*	Ad-hoc Periodic
Survey meter used*	
Date of survey*	
Area monitoring carried out*	--Please Select--
Contamination monitoring carried out*	--Please Select--
Maximum radiation level recorded*	--Please Select--
Maximum contamination level recorded*	--Please Select--

For guidelines regarding filling up of all other forms after regularization, refer to **Guidelines for New Facilities**.

Guidelines for New Facilities

Guidelines for licensing procedures for New Facilities are as follows:

1. Approval of Layout

To apply for the layout, please login to your account. Menus are available to the left of your screen. Go to the menu **Regulatory Forms** → **Nuclear Medicine** → **Site & Layout Plan Approval** as shown below;

Your Role is: **Employer, Licensee**
 Institute Name: **GETWELL SOON2 (MH-20810)**
 Last Successful Login: **21/04/2015**
 Your Logged in profile is: **Nuclear Medicine--Nuclear Medicine Facility**

Change Password			Site & Layout Plan Approval
Instrument Management			Intimation of Available Equipments/Installations
My Applications			Application for Source Procurement
My Casefiles			Source Procurement Intimation
My Drafts	Common Forms		Application for Licence
My Institute Details	Nuclear Medicine		QA/QC Report
Regulatory Forms	Transport		Radiation Survey Report
User management		08/04/2015 03:38 PM	Application For Decommissioning/Disposal
View Inspection Documents		08/04/2015 03:01 PM	Application for Decommissioning Intimation

08/04/2015 03:38 PM You have successfully submitted Application for supplier authorisation with
 08/04/2015 03:01 PM Your application for supplier authorisation (ref no. 15-5121) is Approved.

Click on **Site & Layout Plan Approval** and the application form will appear

NUCLEAR MEDICINE FACILITY > APPLICATION FOR SITE AND LAYOUT PLAN APPROVAL

List of Available Installations | **General Details**

All fields marked by * are mandatory

Have you obtained Site and Layout approval from AERB for all your available installations on or before 31/01/2015*	--Please Select--
Layout application submission for*	--Please Select--
Whether technical expert is within the institute?*	--Please Select--
Name of the technical expert *	

Fill up the form as required. Important points in each tab are mentioned below:

Tab 1: List of Available Installation

This Tab will show you the list of all installations (e.g. PET, SPECT, PET-CT, High Dose Therapy etc) available with you and registered with AERB. Check for any discrepancies.

Tab 2: General Details

- **Have you obtained Site and Layout from AERB for all your available installations on or before 31/01/2015?:** Choose 'No' as the application is new and not approved by AERB.

- **Layout application submission for:** Choose **New Application** for approval of newly proposed layout.
Choose **Modification of Approved layout** for structural modification or change in orientation without change in installations in a preapproved/existing layout.
Choose **Addition of New Installation** in case of addition of new installation in a preapproved/existing layout
Choose **Deletion of Existing Installation** in case of deletion of installation in a preapproved/existing layout for which **Intimation of Available Equipment/Installation** not yet submitted

Note that, Modification /Addition /Deletion will be applicable for regularized Layout Approvals also

On selection of New/Modification/Addition/Deletion, further related fields will be prompted

New Application

- **Application Submission For:** Choose all the installations/equipments required from the drop down list. Use **Add Row** for multiple selection. Note that **Number of Each Installations** for **LDT, HDT. Beta-Therapy & Non- Imaging Techniques** are by default **'1'** and can't be modified.
Fill the details prompted on your selection.

Note: Carefully select all the installations as the radioisotopes and its quantity available to you for permission in the later stages will be based on your selection

NUCLEAR MEDICINE FACILITY APPLICATION FOR SITE AND LAYOUT PLAN APPROVAL

List of Available Installations | **General Details** | Checklist | Attachments

All fields marked by * are mandatory

Have you obtained Site and Layout approval from AERB for all your available installations on or before 31/01/2015*

Layout application submission for*

Whether technical expert is within the institute?*

Name of the technical expert*

Application Submission For*	Number of Each Installations*
<input type="text" value="Non-Imaging Techniques"/>	<input type="text" value="1"/>
<input type="text" value="PET-CT"/>	<input type="text" value="2"/>
<input type="text" value="HDT(High Dose Therapy)"/>	<input type="text" value="1"/>

Add row | Delete row

PET/PET-CT/PET-MRI Details

Proposed combined workload(number of patients/week)*

HDT Details

Total number of beds for HDT*

Minimum capacity of single delay tank(litres)*

Whether more than *1* delay tank is indicated in the layout plan?*

Whether plumbing line to the delay tank/sewerage is indicated in the attached layout plan?*

Freeze | Close | Reset

Modification of Approved layout

- **Reference number of Site and Layout approval:** Select reference of layout for which you require modification. Other details of modification will be sought after selection.
- **Brief Description:** Give a brief description of proposed modifications/changes from the existing layout

NUCLEAR MEDICINE FACILITY APPLICATION FOR SITE AND LAYOUT PLAN APPROVAL

List of Available Installations | **General Details** | Checklist | Attachments

All fields marked by * are mandatory

Have you obtained Site and Layout approval from AERB for all your available installations on or before 31/01/2015*

Layout application submission for*

Whether technical expert is within the institute?*

Name of the technical expert*

Reference number of Site and Layout approval*

Brief description*

Addition of New Installation

- **Reference number of Site and Layout approval:** Select reference of layout in which you require addition of new installation. Other details will be sought after selection.
- **Application Submission For:** Choose all the installations/equipments to be added from the drop down list. Use **Add Row** for multiple selection. Give related details

sought considering all the equipments available and proposed. (e.g. If you have an already existing PET with workload 60 in the layout and you want to add another one with workload 60, choose one PET under **Application Submission For** and write 120 in **Proposed Combined Workload**.

Deletion of Existing Installation

- Similar to the earlier one. Please note that this option can be exercised for the installation only if **Intimation of Available Equipment/Installation** not yet submitted. For modification in layout after **Deletion of Existing Installation**, option for **Modification of Approved layout** can be exercised.

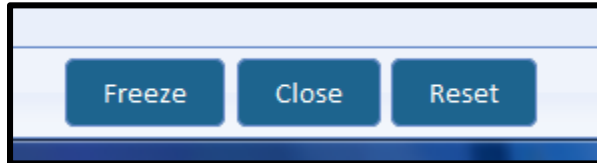
Tab 3: Checklist

Checking the check boxes in the **Checklist** are mandatory for submission. Please go carefully through all the points on the checklist to avoid rejection of application from AERB end.

Tab 4: Attachment

Attachments are context based. Help menu is available with the attachment tab.

Please note that on completion of filling up the form you are required to Freeze/Submit the application by clicking on the options available below the screen.



2. Intimation of Available Equipment

- Every institution needs to intimate the equipment (e.g. PET, SPECT etc) as and when it is available with the institution and installed. Similarly, installations (HDT, LDT, Beta-Therapy etc) also need to be intimated through this screen. Give all the details as sought in the screen and **SUBMIT**.
- The system will automatically register the details as provided.

A screenshot of a user dashboard. The top left shows user information: 'Your Role is: Employer', 'Institute Name: Advanced Centre for Treatment, Research & Education in Cancer', 'Last Successful Login: 06/04/2015', and 'Your Logged in profile is: Nuclear Medicine--Nuclear Medicine Facility'. A dropdown menu is open, listing various options like 'Site & Layout Plan Approval', 'Intimation of Available Equipments/Installations', 'Application for Source Procurement', etc. A red arrow points from the 'Intimation of Available Equipments/Installations' option down to the 'Equipment Details' form below.

Date and Time	Message to User
06/04/2015 01:39 PM	Your application for Source Type registration (ref no. 15-5061) is Approved. Approval No is 15-COMSUPPADDDEL-4372.
06/04/2015 01:34 PM	Your application for supplier authorization (ref no. 15-5060) is Approved. Approval No is 15-COMSUPPADDDEL-4370.
10/03/2015 09:14 AM	You have successfully submitted Notification for Trainee Radiographer with Application No. 15-4938 for Mrs. TRAINEE RADIOGRAPHER.

A screenshot of the 'Equipment Details' form. It contains several input fields with red asterisks indicating required fields: 'SLA reference no*', 'Installation ID*', 'Model*', 'Supplier*', 'Sr.no*', 'Maximum kVp', 'Maximum mA', and 'Date of procurement/available since*'. Each field has a corresponding empty input box and a three-dot menu icon to its right.

SLA reference no*	<input type="text"/>	...
Installation ID*	<input type="text"/>	...
Model*	<input type="text"/>	...
Supplier*	<input type="text"/>	...
Sr.no*	<input type="text"/>	
Maximum kVp	<input type="text"/>	
Maximum mA	<input type="text"/>	
Date of procurement/available since*	<input type="text"/>	

3. Application for Source Procurement

- On successful intimation of available equipment, eLORA takes note of availability of the equipments/installations with the facility.
- Application for procurement of source can be made by following the path
Menu —→ **Regulatory Forms** —→ **Nuclear Medicine** —→ **Application for Source Procurement** as shown below;

The screenshot shows the user interface of the eLORA system. At the top, it displays the user's role as 'Employer' and the institute name as 'Advanced Centre for Treatment, Research & Education in Cancer'. The user is logged in as 'Nuclear Medicine--Nuclear Medicine Facility'. A dropdown menu is open, showing the navigation path: 'Regulatory Forms' -> 'Nuclear Medicine' -> 'Application for Source Procurement', which is highlighted with a red circle. Other menu items include 'Site & Layout Plan Approval', 'Intimation of Available Equipments/Installations', 'Source Procurement Intimation', 'Application for Licence', 'QA/QC Report', 'Radiation Survey Report', 'Application For Decommissioning/Disposal', and 'Application for Decommissioning Intimation'. Below the menu, there are sections for 'Change Password', 'Instrument Management', 'My Applications', 'My Casefiles', 'My Drafts', 'My Institute Details', 'Regulatory Forms', 'User management', and 'View Inspection Documents'. A table at the bottom shows a list of non-compliance issues and a successful RSO nomination.

09/04/2015 10:52 AM	Non Compliance has been raised for your institute with reference no [MH-0000
09/04/2015 10:52 AM	Non Compliance has been raised for your institute with reference no [MH-0000
08/04/2015 04:49 PM	You have successfully freed RSO Nomination with application no. 15-5140

The following form will appear in your screen for application;

The screenshot shows the 'Application for Source Procurement' form. The form has four tabs: 'Worker Details', 'Instrument Details', 'Source Details', and 'Attachments'. The 'Source Details' tab is active. The form contains the following fields:

- Type of source to be procured* (Dropdown menu: --Please Select--)
- Procurement for* (Dropdown menu: --Please Select--)
- Source* (Text input field with a search icon)
- Source specification (Text input field)
- Activity* (Dropdown menu: --Please Select--)

At the bottom of the form, there are three buttons: 'Submit', 'Close', and 'Reset'.

Important points in each Tab are mentioned below:

Tab 1: Worker Details & Tab 2: Instrument Details

These tabs are for verification only. Any changes in the details should be done in respective menus available in e-LORA e.g. **Instrument Management & User Management**.

Tab 3: Source details

Details of the source sought are to be provided in this Tab

- **Type of source to be procured:** Select **Unsealed** or **Sealed** as required
- **Procurement for:** Choose between **Clinical Source, QA Source, Radiation Survey Source & Check Source**
- **Source:** Select which Source you want to procure from LOV. The **Source specification** will be automatically captured based on your selection
- **Activity:** Mention **Activity** of the source and select **Unit**
- **Available Installation ID:** Multiselect installation IDs where you intend to use the source. The installations will be shown to you based on availability and choice you mentioned above.
- **Frequency:** Select the frequency of procurement of the source. This field is applicable for **Unsealed** source procured for **Clinical Use** only.

Note: 1. Application for procurement of a source with specification for clinical use can be done once for the year per facility. For any change in activity or other, the permission should be cancelled and fresh application to be submitted again.
2. Only Licensed facilities can apply for source procurement for Clinical Use.

4. Source Procurement Intimation

Each time a user wants to procure radioactive source for Nuclear Medicine practices from a certain supplier in the country, it needs to raise request through e-LORA. Follow the path mentioned below for the relevant form;

Menu → **Regulatory Forms** → **Nuclear Medicine** → **Source Procurement Intimation**

Your Role is: **Employer, Licensee**
 Institute Name: **GETWELL SOON2 (MH-20810)**
 Last Successful Login: **27/04/2015**
 Your Logged in profile is: **Nuclear Medicine--Nuclear Medicine Facility**

Change Password		Site & Layout Plan Approval	
Instrument Management		Intimation of Available Equipments/Installations	
My Applications		Application for Source Procurement	
My Casefiles		Source Procurement Intimation	BOX
My Drafts	Common Forms	Application for Licence	
My Institute Details	Nuclear Medicine	QA/QC Report	
Regulatory Forms	Transport	Radiation Survey Report	Mess
User management		Application For Decommissioning/Disposal	val with
View Inspection Documents		Application for Decommissioning Intimation	ved. App

Date and Time	
08/04/2015 03:38 PM	You have successfully submitted Application for supplier authorisation with appli
08/04/2015 03:01 PM	Your application for supplier authorisation (ref no. 15-5121) is Approved. Appr
08/04/2015 02:58 PM	You have successfully submitted Application for supplier authorisation with appli

The **Click** will navigate you to the following screen;

NUCLEAR MEDICINE FACILITY APPLICATION FOR SOURCE PROCUREMENT INTIMATION

Procurement Intimation Details | Source Procurement Details

Select	Procurement Reference No.	Intimation Reference No.	Proposed date of procurement	Source Name	Source Category	Source Type	Specification
<input type="radio"/>	14-PROC-INTIMATION-2	14-PROC-INFO-2	16/12/2014	F-18	Quality Assurance Source	UNSEALED	Fluorine-18 labelled radiopharmaceutical
<input type="radio"/>	14-PROC-INTIMATION-1	14-PROC-INFO-1	24/11/2014	Sr-90	Check Source	SEALED	Check Source

Showing 1 to 2 of 2 entries

Following are the guidelines for filling up the form;

Tab 1: Procurement Intimation Details

The Tab gives details of all the **Source Procurement Intimations** already raised by the User. The data can be modified as applicable from this screen.

Tab 2: Source Procurement Details

Fill up the required form as given below to submit the **Source Procurement Intimation** and click on **Submit**.

- **Reference No of Procurement:** Select appropriate procurement approval from AERB.
- **Source / Specification /Authorized Activity / Frequency:** Will be auto-filled based on earlier selection.
- **Proposed date of procurement:** Provide the date of proposed procurement.
- **Proposed activity of procurement:** Provide the activity you wish to procure.

- **Supplier:** Select supplier from LOV

Note: 1. Submitted data will be reflected in Supplier’s dashboard, based on which the Supplier’s will supply. Please note that this provision is only to register and regulate use of radioactivity in e-LORA. You should confirm with the supplier regarding the order.

2. Multiple entries are possible. User may schedule supply for entire year.

3. The entries will be modifiable for clinical sources only

5. Application for License

To apply for License for the installations, follow the path **Menu** → **Regulatory Forms** → **Nuclear Medicine** → **Application for License** and **Click** as shown below.

Date and Time	Description
08/04/2015 03:38 PM	You have successfully submitted Application for supplier authorisation with ap
08/04/2015 03:01 PM	Your application for supplier authorisation (ref no. 15-5121) is Approved. Ap
08/04/2015 02:58 PM	You have successfully submitted Application for supplier authorisation with ap

The following page will appear on your screen. Fill the same as instructed:

Tab 1: Worker Details, Tab 2: Instrument Details & Tab 3: Installation Details are for information and verification only.

Tab 4: General Details

- **Have you obtained Licence from AERB for all your available installations on or before 31/01/2015?:** Select 'No' for new License
- **License for:** Select whether License is for **Installation** or **Check Source**

The screenshot shows a web-based form with the following fields and controls:

- Worker Details
- Instrument Details
- Installation Details
- General Details** (Active Tab)
- Attachments

Form Fields:

- Have you obtained Licence from AERB for all your available installations on or before 31/01/2015?*: YES
- Date of issuance*
- Approval valid till*
- Approval Reference Number*
- Licence for*: --Please Select-- (Dropdown menu with options: --Please Select--, Installation, Check Source)

Buttons: Freeze, Close, Reset

On selection of **Installation**

- **Installation ID:** Select from LOV the installation you want to apply for
- **Type of Installation / Make/ Model / Serial No / Max kVp / Max mA:** Will be auto-populated based on your selection
- **Reference No of QA/QC report:** QA/QC report should be selected from LOV. For guidance to how to upload QA/QC report see the relevant section.
- **Reference No of Radiation Survey report:** Radiation Survey report should be selected from LOV. For guidance to how to upload Radiation Survey report see the relevant section.

NUCLEAR MEDICINE FACILITY APPLICATION FOR LICENCE

Worker Details Instrument Details Installation Details **General Details** Attachments

Have you obtained Licence from AERB for all your available installations on or before 31/01/2015?*	YES	▼
Date of issuance*		
Approval valid till*		
Approval Reference Number*		
Licence for*	Installation	▼
Installation ID*		...
Type of Installation		
Make		
Model		
Serial No		
Max kVp		
Max mA		
Reference No of QA/QC report*		... ?
Reference No of Radiation Survey report*		...

Freeze Close Reset

On selection of **Check Source**,

- **Source ID:** Select from LOV the source you want to apply for
- **Specification / Make / Model / Radioisotope / Supplier / Maximum Activity:** Will be auto-populated based on your selection

Note: The Application should be processed as described in the application for New Layout Approval earlier in this document.

NUCLEAR MEDICINE FACILITY APPLICATION FOR LICENCE

Worker Details Instrument Details Installation Details **General Details** Attachments

Have you obtained Licence from AERB for all your available installations on or before 31/01/2015?*	YES
Date of issuance*	
Approval valid till*	
Approval Reference Number*	
Licence for*	Check Source
Source ID*	
Specification	
Make	
Model	
Radioisotope	
Supplier	
Maximum Activity	
Reference No of QA/QC report*	

Freeze Close Reset

6. QA/QC Report & Radiation Survey Report

For detailed guidance about uploading of QA/QC Report & Radiation survey Report refer to guidelines for **QA/QC Report & Radiation survey Report** under Guidelines for **Regularization of Already Existing Nuclear Medicine Facilities**.

7. Application For Decommissioning / Disposal

In case you wish to decommission an installation or dispose of a sealed source, follow the mentioned path for application,

Menu → **Regulatory Forms** → **Nuclear Medicine** → **Application for Decommissioning / Disposal** as shown below;

Your Role is: **Employer, Licensee**
 Institute Name: **GETWELL SOON2 (MH-20810)**
 Last Successful Login: **13/04/2015**
 Your Logged in profile is: **Nuclear Medicine--Nuclear Medicine Facility**

Change Password		Site & Layout Plan Approval	
Instrument Management		Intimation of Available Equipments/Installations	
My Applications		Application for Source Procurement	
My Casefiles		Source Procurement Intimation	BOX
My Drafts		Application for Licence	
My Institute Details		QA/QC Report	
Regulatory Forms		Radiation Survey Report	Message
User management		Application For Decommissioning/Disposal	Approval with Ap
View Inspection Documents		Application for Decommissioning Intimation	red. Appro
		or supplier authorisation (ref no. 15-5121) is Approved. Approva	
		fully submitted Application for Source Type Approval with applica	
	08/04/2015 03:38 PM	You have successfully submitted Application for supplier authorisation with applicati	
	08/04/2015 03:01 PM	Your application for supplier authorisation (ref no. 15-5121) is Approved. Approva	
	08/04/2015 02:58 PM	You have successfully submitted Application for supplier authorisation with applicati	
	28/11/2014 03:36 PM	You have successfully frozen application for Site&LAYOUT plan approval with Appli	

The following screen will appear in your screen,

Decommissioning Details

In case of decommissioning of PET,PET-CT or PET-MR of an existing SLA approval which is having more than one PET,PET-CT or PET-MR you required mandatorily.

All fields marked by * are mandatory

Decommissioning/Disposal of*

Equipment ID/Source ID(for sealed source)*

Purpose of decommissioning*

Concurrence obtained from the disposal agency/supplier for accepting the residual radiation source ?*

Additional information*

Installation ID
 --Please Select--
 Source Identification Number
 Installation ID

--Please Select--

Browse... No file selected. Clear

Please fill up the same as per the directions as follows and **Submit**.

Tab: Decommissioning Details:

- **Decommissioning Disposal of:** Select appropriately Between **Source Identification Number & Installation ID**
- **Equipment ID/Source ID:** Select the one you want to decommission
- **Purpose of Decommissioning:** Briefly give the reason for decommissioning
- **Concurrence obtained from the local disposal agency/supplier for accepting the residual radiation source?:** Select **Yes** or **No**

- **Additional Information:** Attach reports or anything you want to share with AERB. If the above selection is **Yes**, proof may be attached.

8. Application for Decommissioning Intimation

On actual decommission /disposal of an installation or source AERB should be intimated about the same by this application. Follow the path;

Menu → **Regulatory Forms** → **Nuclear Medicine** → **Application for Decommissioning Intimation** as shown below;

The screenshot shows a user interface with the following elements:

- User Profile:** Your Role is: **Employer, Licensee**; Institute Name: **GETWELL SOON2 (MH-20810)**; Last Successful Login: **13/04/2015**; Your Logged in profile is: **Nuclear Medicine--Nuclear Medicine Facility**.
- Navigation Menu:**
 - Change Password
 - Instrument Management
 - My Applications
 - My Casefiles
 - My Drafts
 - My Institute Details
 - Regulatory Forms
 - User management
 - View Inspection Documents
- Regulatory Forms Sub-menu:**
 - Common Forms
 - Nuclear Medicine
 - Transport
- Application List:**
 - Site & Layout Plan Approval
 - Intimation of Available Equipments/Installations
 - Application for Source Procurement
 - Source Procurement Intimation
 - Application for Licence
 - QA/QC Report
 - Radiation Survey Report
 - Application For Decommissioning/Disposal
 - Application for Decommissioning Intimation
- Recent Activity Log:**
 - 08/04/2015 03:38 PM: You have successfully submitted Application for supplier authorisation with
 - 08/04/2015 03:01 PM: Your application for supplier authorisation (ref no. 15-5121) is Approved.
 - 08/04/2015 02:59 PM: You have successfully submitted Application for supplier authorisation with

Fill up the following data available in the screen as shown below;

The screenshot shows the 'Decommissioning Intimation Details' form with the following fields:

- Decommissioning Approval No ***: Input field with a search icon (All fields).
- Make**: Input field.
- Model**: Input field.
- Concurrence letter***: File upload field with 'Browse...' and 'Clear' buttons. Status: No file selected.

At the bottom of the form, there are three buttons: **Submit**, **Close**, and **Reset**.

Tab: Decommissioning Intimation Details

- **Decommissioning Approval No:** Select from LOV
- **Make / Model:** Will be auto-populated based on your selection
- **Concurrence Letter:** For Source, give Concurrence letter for disposal; for installation, attach report of decommissioning

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